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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

PREBILIC, PAUL B

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 07/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/289,000

Applicant(s)

BLATT, GERALD

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-10 and 24-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-10 and 24-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☒ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Drawings

The proposed drawing correction filed on April 30, 2002 has been disapproved because it is not in the form of a pen-and-ink sketch showing changes in red ink or with the changes otherwise highlighted. See MPEP § 608.02(v).

Figures 1B to 1E should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6, 8-10, and 25-28 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

In particular, claim 1, line 15, claim 8, line 14, claim 25, line 15, and claim 26, line 15, the step of "forming fibroblast . . ." is non-statutory because it is a naturally occurring process. Rather, it could be claimed as "allowing formation of a fibroblast . . ." in order to overcome this objection.

Regarding claims 1-6 and 25-27, claim 1, line 13, claim 25, line 13, and claim 26, line 13, the step of "while resorbing the implant" is non-statutory because it claims a natural process as if it is a part of the invention. Rather, the language "while allowing resorption of the implant" could be used to overcome this rejection.

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Claim Objections

Claims 8-10 and 28 are objected to because of the following informalities: In claim 8, last subparagraph, the language "while using the joint forming fibroblast" is not understood. To overcome this objection, the Examiner suggesting inserting a comma between "joint" and "forming." Appropriate correction is required.

Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-6, 8-10, and 24-31 are rejected under 35 U.S.C. 102(b) as anticipated by Cohen (US 5,207,712) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cohen (US 5,207,712) alone. Cohen (US 5,207,712) anticipates the claim language wherein the resection of bone ends or the holes drilled into the bone ends expose the cancellous bone surface and the solid sphere and rods allow both for the joint to flex and extend after implantation (see Col. 4, lines 38 and 39) and the ball (4)

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provides a sliding surface for the joint ends; see the whole document, especially Col. 3, lines 18-20; Col. 4, lines 3-39 and Figures 1-3 and 8-11.

Alternatively, one could view the ball (4) as not providing a sliding surface because it is not explicitly stated as providing such. However, the Examiner posits that one viewing this embodiment would be led to the conclusion that the ball (4) obviously functions as a stop and sliding surface for the resected bone ends because the joint flexes and extends around the ball surface; see column 4, lines 38-39.

With regard to claims 8 and 9, Applicant is directed to Figure 1 and especially Figure 2 for claim 8. It is noted that the first and second face of Cohen is on opposed sides of the spacer such that it reads on the claim language.

With regard to claim 24 specifically, the Examiner posits that a period of 6 to 7 months would be sufficient to allow all the natural processes of the permitting step as claimed to take place; see Col. 2, lines 45-48.

With regard to claims 4, 10, and 25 specifically, the estimating step as claimed is inherently or implicitly present in Cohen who makes his device for a particular joint type so that as much regrowth between the joints can take place.

Claims 2 and 3 are rejected under 35 U.S.C. 103 as being unpatentable over Cohen (US 5,207,712) in view of Delcommune et al (US 5,007,939). Cohen meets the claim language except for the use of lactic acid polymer or copolymer as claimed. Delcommune et al, however, teaches that it has been known to use lactic acid polymer or copolymer for resorbable bone repair devices. Hence, it is the Examiner's position that it would have been obvious to one of ordinary skill in the art to use lactic acid

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polymer or copolymer in place of in addition to the polymer of Cohen for the same reasons that Delcommune et al uses the same and in order to further reduce the cost of making the device.

Response to Arguments

Applicant's arguments filed April 30, 2002 have been fully considered but they are not persuasive.

In particular, Applicants argue that the rod(s) of Cohen would have to be sheared off in order to obtain sliding motion. However, the Examiner asserts that Applicant is assuming that the rod(s) is rigid and inflexible. There is no actual evidence of these properties only arguments stating such. Furthermore, Cohen suggests otherwise by stating that flexion and extension occur after implantation; see column 4, lines 38-39. Due to this disclosure of Cohen, the Examiner maintains that objective actual proof is necessary to show that Cohen lacks sliding motion and fails to perform in the manner Cohen states.

It is noted that Declarant Ronald W. Smith never actually used or tested the Cohen implant, but rather, speculates that it would not result in a sliding motion. The Examiner maintains that this is insufficient evidence in view of explicit statements in the Cohen disclosure.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9301.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic
Primary Examiner
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